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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,724	10/01/2001	Kenneth W. Kinzler	01107.00193	3707

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BANNER & WITCOFF  
1001 G STREET N W  
SUITE 1100  
WASHINGTON, DC 20001

EXAMINER

ASHEN, JON BENJAMIN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,724

Applicant(s)

KINZLER ET AL.

Examiner

Jon B. Ashen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-29 and 56-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 27-29, 56-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 27-28, 56, 58 and 60 are drawn to a method of treating a neoplastic cell or a cell having an amplified human MDM2 gene, elevated levels of MDM2 mRNA expression or elevated levels of MDM2 protein comprising administering antisense oligonucleotides complementary to contiguous nucleotides of a human MDM2 mRNA selected from nucleotides 1-312 of SEQ ID NO: 2, that inhibit transcription or translation of a human MDM2 gene, classifiable in class 514 subclass 44.
  - II. Claims 29, 57, 59 and 61 are drawn to a method of treating a neoplastic cell or a cell having an amplified human MDM2 gene, elevated levels of MDM2 mRNA expression or elevated levels of MDM2 protein comprising administering antisense oligonucleotides complementary to contiguous nucleotides of a human MDM2 mRNA selected from nucleotides 1-312 of SEQ ID NO: 2, that inhibit transcription or translation of a human MDM2 gene, classifiable in class 514 subclass 44.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of group I is a method of treating a cell comprising administering an antisense oligonucleotide complementary to particular nucleotides of a human MDM2 mRNA. The invention of group II is a method of treating a cell comprising administering a triple strand forming oligonucleotide complementary to particular nucleotides of a human MDM2 gene.

In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. A method of treatment comprising administration of an antisense oligonucleotide that inhibits gene expression operates thru the delivery of a reverse complementary nucleic acid (antisense) to a cell in which the gene of interest is expressed and leads, via typical hydrogen bonding of base pairs, to hybridization between the antisense sequence and the mRNA of the target gene. A method of treatment comprising administration of an triple strand forming oligonucleotide that inhibits gene expression operates thru the delivery of a sense or antisense oligonucleotide to a cell in which the gene of interest is expressed and leads, via Hoogsten-bond formation, to the binding of the triple strand forming oligonucleotide to the major groove of duplex DNA in a sequence specific manner. This binding is constrained in requiring the presence of contiguous runs of purines and pyrimidines (10-30 nt in length) on opposing strands of the DNA duplex for triplex bond formation. Therefore, the structure of an oligonucleotide used in a method of treatment that

operates by antisense oligonucleotide inhibition of transcription or translation will be different from the structure of an oligonucleotide used in a method of treatment that operates by triple strand forming oligonucleotide inhibition of transcription or translation, not only are the inventions of groups I and II patentably distinct, but a different search would be required in examination of both methods.

3. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and would require divergent searches of sequence and literature databases placing an undue administrative burden on the examiner, restriction for examination purposes as indicated is proper.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

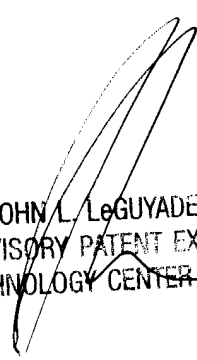
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contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba

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JOHN L. LEGUYADEH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600